



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449/APTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 7

Application Number	10/626,434
Filing Date	07/24/2003
First Named Inventor	Andrew Joseph Friedman
Group Art Unit	
Examiner Name	N/A
Attorney Docket Number	PRD-0007-US-CIP

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code ² (if known)			
YU		4,264,575		Zimmerman et al.	04-28-1981	
		4,390,531		Edgren	06-28-1983	
		4,762,717		Crowley, Jr.	08-09-1988	
		5,043,331		Hirvonen et al.	08-27-1991	
		5,098,714	A	Wright et al.	03-24-1992	
		5,108,995	A	Casper	04-28-1992	
		5,208,225	A	Boissonneault et al.	05-04-1993	
		5,211,952	A	Spicer et al.	05-18-1993	
		5,756,490	A	Lachnit et al.	05-26-1998	
		5,770,226	A	Hughes, Jr. et al.	06-23-1998	
		5,876,746	A	Jona et al.	03-02-1999	
		5,898,032	A	Hodgen	04-27-1999	
		5,962,021	A	Hughes, Jr. et al.	10-05-1999	
		5,972,377	A	Jona et al.	10-26-1999	
		5,980,940	A	Spona et al.	11-09-1999	
		6,027,749	A	Schmidt-Gollwitzer et al.	02-22-2000	
		6,071,531	A	Jona et al.	06-06-2000	
		6,077,840	A	Kurihara et al.	06-20-2000	
		6,077,873	A	Loozen	06-20-2000	
		6,110,471	A	Conti et al.	08-29-2000	

Examiner Signature	<i>Yong Hong</i>	Date Considered	1/11/06
-----------------------	------------------	--------------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 7

Application Number	10/626,434
Filing Date	07/24/2003
First Named Inventor	Andrew Joseph Friedman
Group Art Unit	
Examiner Name	N/A
Attorney Docket Number	PRD-0007-US-CIP

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code ² (if known)			
YL		6,139,873	A	Hughes, Jr. et al.	10-31-2000	
		6,177,416	B1	Laurent et al.	01-23-2001	
		6,180,803	B1	Piasco et al.	01-30-2001	
		6,225,297	B1	Stockemann et al.	05-01-2001	
		6,312,722	B1	Schmidt-Gollwitzer et al.	11-06-2001	
		6,313,180	B1	Loozen	11-06-2001	
		6,326,392	B1	Gast et al.	12-04-2001	
		6,340,688	B1	Chwalisz et al.	01-22-2002	
		6,362,237	B1	Chwalisz et al.	03-26-2002	
		6,416,778	B1	Ragavan et al.	07-09-2002	
		6,451,778	B1	Gast	09-17-2002	
		6,451,779	B1	Hesch	09-17-2002	
		6,479,475	B1	Gast	11-12-2002	
		6,500,814	B1	Hesch	12-31-2002	
		6,506,742	B2	Wong et al.	01-14-2003	1
		2001/0027189	A1	Bennink et al.	10-04-2001	
		2002/0035099	A1	Grubb et al.	03-21-2002	
		2002/0061875	A1	Gast et al.	05-23-2002	
		2002/0103179	A1	Wong et al.	08-01-2002	
		2002/0177580	A1	Van Beek et al.	11-28-2002	
		2003/0018018	A1	Hodgen et al.	01-23-2003	

Examiner Signature	<i>[Signature]</i>	Date Considered	1/11/06
-----------------------	--------------------	--------------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 7

Application Number	10/626,434
Filing Date	07/24/2003
First Named Inventor	Andrew Joseph Friedman
Group Art Unit	
Examiner Name	N/A
Attorney Docket Number	PRD-0007-US-CIP

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶
		Office ³	Number ⁴	KindCode ⁵				
YC		EP	0 911 029	B2	Medical College of Hampton Roads	04-28-1999		
YC		EP	1 275 394	A2 & A3	Medical College of Hampton Roads	01-15-2003		

Examiner Signature	<i>Yong Chong</i>	Date Considered	1/11/06
-----------------------	-------------------	--------------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 4 of 7

Application Number	10/626,434
Filing Date	07/24/2003
First Named Inventor	Andrew Joseph Friedman
Group Art Unit	
Examiner Name	N/A
Attorney Docket Number	PRD-0007-US-CIP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
VL		ABRAHAM, S. et al.: Menstruation, menstrual protection and menstrual cycle problems; The Med. J. of Australia, Vol. 142, February 18, 1985, pp. 247-251.	
		AL-AZZAWI F.: Pulsed estrogen therapy: from cellular mode of action to tissue effects; Climacteric 2002 Jun;5 Suppl 2:27-31.	
		ANDERSON, F.D.: The Safety and Efficacy of Seasonale, a Novel 91-Day Extended Oral Contraceptive Regimen; Obstet & Gynecol, April 2002; Vol 99, No. 4 (suppl); p. 26S.	
		CACHRIMANIDOU, A-C et al.: Long-interval treatment regimen with a desogestrel-containing oral contraceptive; Contraception 1993;48, September, pp. 205-216.	
		CACHRIMANIDOU, A-C et al.: Hemostasis profile and lipid metabolism with long-interval use of a desogestrel-containing oral contraceptive; Contraception 1994;50, August, pp. 153-165.	
		CLARKE, A.K. et al.: The Debate Regarding Continuous Use of Oral Contraceptives; The Annals of Pharmacotherapy 2001 November, Vol. 35, pp. 1480-1484.	
		DAVIES, G.C. et al.: Ovarian activity and bleeding patterns during extended continuous use of a combined contraceptive vaginal ring; Contraception 46:269-278, 1992.	
		DE VOOGD, W.S.: Postponement of withdrawal bleeding with a monophasic oral contraceptive containing desogestrel and ethinylestradiol; Contraception August 1991, Vol. 44 No. 2, pp. 107-112.	
		DEN TONKELAAR, I. et al.: Preferred Frequency and Characteristics of Menstrual Bleeding in Relation to Reproductive Status, Oral Contraceptive Use, and Hormone Replacement Therapy Use; Contraception 1999;59, pp. 357-362.	
		FAUSER, B.C.J.M. et al.: Manipulation of Human Ovarian Function: Physiological Concepts and Clinical Consequences; Endocrine Reviews Vol. 18 No. 1, pp.71-106.	
		FINLAY, I.G. et al.: Patterns of contraceptive pill taking in an inner city practice; British Med. J. Vol. 293, 6 September 1986, pp. 599-602.	

Examiner Signature	<i>[Signature]</i>	Date Considered	1/11/06
--------------------	--------------------	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 5 of 7

Application Number	10/626,434
Filing Date	07/24/2003
First Named Inventor	Andrew Joseph Friedman
Group Art Unit	
Examiner Name	N/A
Attorney Docket Number	PRD-0007-US-CIP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
YL		FRANKE, H.R. et al.: The effect of continuous combined 17 β -oestradiol and dihydrodydrogesterone on apoptotic cell death and proliferation of human breast cancer cells in vitro; Eur J. Cancer 2002 Nov;38 Suppl 6:S69-70.	
		GLASIER, A.F. et al.: Amenorrhea associated with contraception -- an international study on acceptability; Contraception 67 (2003), pp. 1-8.	
		GUILLEBAUD, J.: The forgotten pill--and the paramount importance of the pill-free week;	
		HAMERLYNCK, J.V.T.H. et al.: Postponement of withdrawal bleeding in women using low-dose combined oral contraceptives; Contraception March 1987 Vol. 35 No. 3, pp. 199-204.	
		KORNAAT, H. et al.: The acceptance of a 7-week cycle with a modern low-dose oral contraceptive (Minulet®); Contraception February 1992 Vol. 45 No. 2, pp. 119-127.	
		KOVACS, G.T. et al.: A trimonthly regimen for oral contraceptives; The British J. of Family Planning 1994, 19, pp. 274-275.	
		KWIECIEN, M. et al.: Bleeding patterns and patient acceptability of standard or continuous dosing regimens of a low-dose oral contraceptive: a randomized trial; Contraception 67 (2003, pp. 9-13.	
		LOUDON, N.B.: Tricycle Pill regime; IPPF Med. Bull., Mar 19:1979, pp. 2-3.	
		LOUDEN, N.B. et al.: Acceptability of an oral contraceptive that reduces the frequency of menstruation: the tri-cycle pill regimen; British Med. J., 1977, 2, pp. 487-490.	
		MARUO, T. et al.: Vaginal rings delivering progesterone and estradiol may be a new method of hormone replacement therapy; Fertil. Steril. 2002, Nov; 78(5), pp. 1010-1016.	
		MARTINEZ-MANAU TOU, J.: Continuous low dose progestagen for contraception; IPPF Med. Bull. 1968;2(5), pp. 2-3.	
		MILLER, L. et al.: Menstrual Reduction With Extended Use of Combination Oral Contraceptive Pills: Randomized Controlled Trial; Obstetrics & Gynecology Vol. 98, No. 5 Part 1, November 2001, pp. 771-778.	

Examiner Signature	<i>[Signature]</i>	Date Considered	1/11/06
--------------------	--------------------	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 6 of 7

Application Number	10/626,434
Filing Date	07/24/2003
First Named Inventor	Andrew Joseph Friedman
Group Art Unit	
Examiner Name	N/A
Attorney Docket Number	PRD-0007-US-CIP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
YL		MILLER, L. et al.: Continuous Combination Oral Contraceptive Pills to Eliminate Withdrawal Bleeding: A Randomized Trial; Obstetrics & Gynecology, Vol. 101, No. 4, April 2003, pp. 653-661.	
		MILLER, W.B. et al.: Elimination of the Menses: Psychosocial Aspects; J. Psychiat. Res., 1975, Vol. 12, pp. 153-166.	
		MULDERS, T.M. et al.: Ovarian function with a novel combined contraceptive vaginal ring; Hum. Reprod. 2002 Oct;17(10), pp. 2594-2599.	
		RIZK, D.E.E. et al.: Congenital Afibrinogenemia: Treatment of Excessive Menstrual Bleeding With Continuous Oral Contraceptive; Letters and Correspondence, pp. 237-238.	
		ROUMEN, F.: Pleister en ring: twee nieuwe toedieningsvormen van hormonale combinatieanticonceptie; TFO1 '02 16E JAARGANG, No. 2 pp. 32-37. (see English language Summary on p. 37).	
		RUTTER, W. et al.: Women's attitudes to withdrawal bleeding and their knowledge and beliefs about the oral contraceptive pill; The Medical J. of Australia Vol. 149 October 17, 1988, pp. 417-419.	
		SHORT, R.V.: Why menstruate?; Healthright Vol. 4 No. 4 August 1985, pp. 9-12	
		SUCATO, G. et al.: New options in contraception for adolescents; Curr Womens Health Rep 2001 Oct;1(2), pp. 116-23.	
		SULAK, P.J. et al.: Extending the Duration of Active Oral Contraceptive Pills to Manage Hormone Withdrawal Symptoms; Obstetrics & Gynecology Vol. 89, No. 2 February 1997, pp. 179-182.	
		TUMOLO, J.: Manipulating menstruation. Continuous-use OC regimens a secret no more; Adv Nurse Pract 2002 June;10(6): pp. 85-87.	
		VERCELLINI, P. et al.: Cyproterone acetate versus a continuous monophasic oral contraceptive in the treatment of recurrent pelvic pain after conservative surgery for symptomatic endometriosis; Fertility and Sterility Vol. 77, No. 1, January 2002, pp. 52-61.	

Examiner Signature	<i>John Chong</i>	Date Considered	1/11/06
--------------------	-------------------	-----------------	---------

*EXAMINER: Initial reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 7 of 7	Application Number	10/626,434
	Filing Date	07/24/2003
	First Named Inventor	Andrew Joseph Friedman
	Group Art Unit	
	Examiner Name	N/A
	Attorney Docket Number	PRD-0007-US-CIP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
VC		VOLLEBREGT, J.A. et al.: A study on postponement of menses with low-dose combined oral contraceptives--Outcome and acceptability; Adv. Contracept 1985; 1, pp. 207.	
1		Trial Information from Center Watch Clinical Trials Listing Service.	

Examiner Signature	<i>Yang Chong</i>	Date Considered	1/11/06
--------------------	-------------------	-----------------	---------

*EXAMINER: Initial reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.